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Section 5 – 510(k) Summary or 510(k) Statement

K062369

I. General Information

Submitter: IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043-1824
USA

Contact Person: John Jossy
Director of Regulatory Affairs and Quality Assurance

Summary Preparation Date: August 11, 2006

II. Names

Device Names: OcuLight TX

Primary Classification Names: Laser Powered Surgical Instrument; Laser, Ophthalmic

III. Predicate Devices

- IRIS Medical OcuLight GL/GLx (K050562)
- Leminis Inc. Novus Spectra (K022327)
- Adept Medical Concepts, Inc Quanta (K032220)
- Biolitec AG (K002296)

IV. Product Description

The OcuLight TX is a solid state laser that delivers true continuous wave green laser (532 nm) light for otolaryngologic, dermatology, and ophthalmic applications. The integrated system is comprised of the OcuLight TX laser console, various compatible optical fiber delivery devices, and a Footswitch. The laser console contains the laser head, imaging optics, power supplies, control electronics, and firmware. The electronic system is comprised of various sense and control electronics, user controls and displays, and an embedded microprocessor that monitors all system functions. The microprocessor interprets operator commands, formats displays and supervises laser emission. A visible red (630-650 nm) semiconductor diode laser is used for aiming.

V. Indications for Use

The OcuLight TX is intended for use in otolaryngological, dermatological and ophthalmic surgical procedures. In otolaryngology it is indicated for stapedectomy, stapedotomy, myringotomy, lysis of adhesions, control of bleeding, removal of acoustic neuromas, and soft tissue adhesion in micro/macro otologic procedures. In dermatology it is indicated for the treatment of vascular and pigmented skin lesions. In ophthalmology it is indicated for retinal photocoagulation, laser trabeculoplasty, iridotomy, and iridoplasty.

VI. Rationale for Substantial Equivalence

The OcuLight TX shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the OcuLight TX is substantially equivalent to the predicate devices.

VIII. Conclusion

The OcuLight TX was found to be substantially equivalent to the predicate devices.

The OcuLight TX shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2006

IRIDEX Corporation
% Mr. John Jossy
Director, Regulatory Affairs and
Quality Assurance
1212 Terra Bella Avenue
Mountain View, California 94043-1824

Re: K062369
Trade/Device Name: OcuLight TX
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 11, 2006
Received: October 13, 2006

Dear Mr. Jossy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K06 K062369

Device Name: OcuLight TX

Otolaryngology:

The OcuLight TX is intended to be used in ENT surgery for tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis. Indications for use include, but are not limited to:

Stapedectomy,
Stapedotomy
Myringotomy
Lysis of adhesions
Control of Bleeding
Removal of Acoustic Neuromas
Soft Tissue Adhesion in Micro/Macro Otologic Procedures

Dermatology:

The OcuLight TX is intended to photocoagulate issue in dermatological procedures. Indications for use include:

Focal laser treatment of vascular and pigmented skin lesions.

Ophthamology:

The OcuLight TX is intended to photocoagulate ocular tissue in ophthalmic procedures. Indications for use include:

Retinal Photocoagulation
Laser Trabeculoplasty
Iridotomy
Iridoplasty

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062369